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#1655

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Bastian Nuyen et al.

Art Unit : 1655

Serial No. : 09/622,433

Examiner : Randall O. Winston

Filed : May 10, 2002

Title : PHARMACEUTICAL FORMULATION OF A DIDEMNIN COMPOUND

**MAIL STOP AMENDMENT**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form.

Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request.

Applicants wish to bring to the Examiner's attention the following copending U.S. application: Bertino et al., USSN 10/548,710, filed on September 8, 2005.

12/20/2005 BABRAHA1 00000048 09622433

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180.00 DP

**CERTIFICATE OF MAILING BY FIRST CLASS MAIL**

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

December 15, 2005

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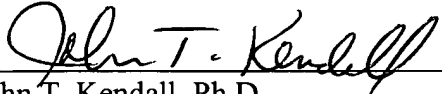
Applicant : Bastian Nuyen et al.  
Serial No. : 09/622,433  
Filed : May 10, 2002  
Page : 2 of 2

Attorney's Docket No.: 14620-12US1 / JC/USP278531

This statement is being filed after a first Office action on the merits, but before receipt of a final Office action or a Notice of Allowance. A check for \$180 in payment of the late submission fee of §1.17(p) is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: December 15, 2005

  
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Substitute Form PTO-1449 (Revised)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 14620-012US1	Application No. 09/622,433
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary) (37 CFR §1.9(b))		Applicant Bastian Nuyen et al.	
		Filing Date May 10, 2002	Group Art Unit 1655

### U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	6,080,877	06/27/00	Swindell et al.			
	AB	6,509,315	01/21/03	Joullié et al.			
	AC	6,610,699	08/26/03	Cavazza et al.			

### Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AD	WO 00/06134	02/10/00	WIPO				

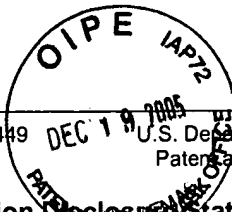
### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AE	Chauhan, D. et al., "Multiple Myeloma Cell Adhesion-Induced Interleukin-6 Expression in Bone Marrow Stromal Cells Involves Activation of NF- $\kappa$ B," <u>Blood</u> , 87(3):1104-1112 (1996)
	AF	"Didemnin B," <u>Drugs of the Future</u> , 20(1):77 (1995)
	AG	Faircloth, G. et al., "Marine (MA) Dipsipeptides (DEP) with Activity (A) against Solid Tumours (ST) Models," <u>Proceedings 8<sup>th</sup> ECCO Congress</u> , 31A (Suppl. 5):S29, Abstract No. 122 (1995)
	AH	Faircloth, G. et al., "Preclinical Development of Aplidine, a Novel Marine-Derived Agent with Potent Antitumor Activity," <u>Annals of Oncology</u> , 9 (Suppl. 2):34, Abstract No. 129 (1998)
	AI	Giovanella, B.C. et al., "Correlation Between Response to Chemotherapy of Human Tumors in Patients and in Nude Mice," <u>Cancer</u> , 52(7):1146-1152 (1983)
	AJ	Hideshima, T. et al., "The Proteasome Inhibitor PS-341 Inhibits Growth, Induces Apoptosis, and Overcomes Drug Resistance in Human Multiple Myeloma Cells," <u>Cancer Res.</u> , 61:3071-3076 (2001)
	AK	Jimeno, J. et al., "Translational Studies Supporting the Clinical Development of Aplidine (APL) in Pediatric Leukemia," <u>Annals of Oncology</u> , 13 (Suppl. 5):19, Abstract No. 65P (2002)
	AL	Mayer, S.C. et al., "Synthesis of New Didemnin B Analogs for Investigations of Structure/Biological Activity Relationships," <u>J. Org. Chem.</u> , 59(18):5192-5205 (1994)
	AM	Mitsiades, C.S. et al., "TRAIL/Apo2L Ligand Selectively Induces Apoptosis and Overcomes Drug Resistance in Multiple Myeloma: Therapeutic Applications," <u>Blood</u> , 98(3):795-804 (2001)
	AN	Mitsiades, C.S. et al., "Activation of NF-kappaB and Upregulation of Intracellular Anti-Apoptotic Proteins via the IGF-1/Akt Signaling in Human Multiple Myeloma Cells: Therapeutic Implications," <u>Oncogene</u> , 21(37):5673-5683 (2002)
	AO	Mitsiades, N. et al., "Molecular Sequelae of Proteasome Inhibition in Human Multiple Myeloma Cells," <u>Proc Natl Acad Sci USA</u> , 99(22):14374-14379 (2002)
	AP	Mitsiades, N. et al., "The Proteasome Inhibitor PS-341 Potentiates Sensitivity of Multiple Myeloma Cells to Conventional Chemotherapeutic Agents: Therapeutic Applications," <u>Blood</u> , 101(6):2377-2380 (2003)
	AQ	Mitsiades, N. et al., "Molecular Sequelae of Histone Deacetylase Inhibition in Human Malignant B Cells," <u>Blood</u> , 101(10):4055-4062 (2003)

Examiner Signature

Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Substitute Form PTO-1449 (Modified)  <b>Information Disclosure Statement</b> by Applicant (Use several sheets if necessary)  (37 CFR §1.98(b))	Attorney's Docket No. <b>14620-012US1</b>	Application No. <b>09/622,433</b>
	Applicant <b>Bastian Nuyen et al.</b>	
	Filing Date <b>May 10, 2002</b>	Group Art Unit <b>1655</b>

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AR	Palangie, T. et al., "Dose-Intense Salvage Therapy After Neoadjuvant Chemotherapy: Feasibility and Preliminary Results," <u>Cancer Chemother. Pharmacol.</u> , 44 (Suppl.):S24-S25 (1999)
	AS	Uchiyama, H. et al., "Adhesion of Human Myeloma-Derived Cell Lines to Bone Marrow Stromal Cells Stimulates Interleukin-6 Secretion," <u>Blood</u> , 82(12):3712-3720 (1993)
	AT	Weiss, R. et al., "A Phase II Trial of Didemnin B in Myeloma," <u>Investigational New Drugs</u> , 12(1):41-43 (1994)

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	